Section 3 510(k) Summary

APR 19 2013

This 510(k) summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K130108

3.1 Date of Submission

January 14, 2013

3.2 Submission Correspondent

Mr. Da Zeng
Xiamen Double Engine Medical Material Co., Ltd.
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3.3 Proposed Device

Device Name: Double Engine Bone Plate and Bone Screw Systems

Classification: II

Product Code: HRS, HWC

Regulation Number: 21 CF 888.3030, 21 CF 888.3040

Review Panel: Orthopedic

Material:

Double Engine Bone Plate and Screw Systems are manufactured from commercially pure titanium and titanium alloy that meet ASTM F67-06, F1472-08e1, and F163-02a.

Intended Use Statement:

Double Engine Bone Plate and Screw Systems are provided non-sterile. Double Engine Bone Plate and Screw Systems are intended for fixation of various bone fracture, including large bone (clavicle, scapula, pelvis, humerus, ulna, radius, femur, tibia, and fibula), and small bone (metacarpals, metatarsals, and phalanges).

3.4 Devices Description

Double Engine Bone Plate System consists of plates in various designs and size. Plates are provided in straight designs and various geometric configurations that are commonly used in traumatic and reconstructive surgery (Table 3.5.1). Plates are provided with screw holes to accommodate non-locking and locking screws. They are named according to both anatomical positions and biomechanical functions of the plates. The sets in size of Double Engine Bone Plate System are divided into four sets: large, small, mini, and reconstruction. The thickness of plates varies from 1.0 to 5.6mm, width from 3.8 to 43.6mm, length from 15.4 to 361mm, and hole number from 2 to 27 holes.

Double Engine Bone Screw System is used either to fasten plates or similar devices onto bones, or, as lag screws, to hold bone fragments together. The screws are differentiated by the manner in which they are inserted into bone, their function, their size, and the type of bone they are intended for. There are three sets of style: cortex, cancellous, and cannulated sets. The screw recess is hexagon or star shaped to allow screw removal and insertion. The thread diameter of screw varies from 1.5 to 7.3mm, total length from 6 to 150mm.

The proposed devices are not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. The sterilization method is presented in the user manual, which was validated per ISO 17665-1: 2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

Table 3.5.1 Plate name and geometric shape of Double Engine Bone Plate System

Plate Name	Geometric Shape
DCP	Narrow, Broad, Lengthening-narrow, Lengthening-broad, Straight
Tubular	Semi-tubular, One third, Quarter
Special	T-shaped, T-buttress, T-oblique, L-shaped, L-buttress, Cobra head, Lateral tibial head, Condylar, Condylar buttress, Spoon, Reconstruction, Reconstruction-curved, Hook, H-shaped, W-shaped cloverleaf, Calcaneal, Y-calcaneal, Adaption

3.5 Predicate Device Information

There are two types of predicate devices used as the control groups to evaluate the performance of proposed devices, including bone plate and bone screw.

Prior to selecting the predicate plates, the finite-element analyses were employed to evaluate the mechanical properties of various bone plates. The analysis results showed that

four types of bone plates have poor mechanical properties and used as the testing representatives of the large, small, mini, and reconstruction sets (Appendix 6). Consequently, these four types of bone plates were used as representative specimens to set the criterion for selecting the predicate plates. The information of the predicate plates is shown in Table 3.6.1.

There are three types of bone screws used as the representatives of Double Engine Bone Screw System, including cortex, cancellous, and cannulated screws. The size and type of the predicate devices are identical to the proposed screws. The information of the predicate screws is shown in Table 3.6.2.

Table 3.6.1 Information of the predicate plates used in this submission

Predicate Set	K No.	Company Name	Device Name
Large	K010766	Synthes (USA)	Synthes (USA)Large Fragment Locking Compression Plate (LCP) System-T Plate
Small	K041860	Synthes (USA)	Synthes (USA)LCP Proximal Humerus Plate, Long
Mini	K063049	Synthes (USA)	Synthes (USA)Modular Mini Fragment LCP System
Reconstruction	K092889	Syntec Scientific Corporation	Syntec Osteo Plate and Screw Fixation

Table 3.6.2 Information of the predicate screws used in this submission

Predicate Set	K No.	Company Name	Device Name
Cortex	K043185	Synthes (USA)	Synthes 3.5mm Cortex Screws
Cancellous	K061621	Synthes (USA)	Synthes (USA) 6.5 mm Cancellous Screws
Cannulated	K963192	Synthes (USA)	Synthes Sterile 3.5mm and 4.0 mm Cannulated Screws

3.6 Non-Clinical Tests Conclusion

Non-clinical tests included finite-element analyses and mechanical tests. Finite-element analyses were made to support that the four selected bone plates were the representative of proposed device. Mechanical tests were completed to demonstrate that performances of four selected bone plates and three bone screws were subsequently equivalent to or better than the predicate devices. The results of non-clinical tests demonstrate the Double Engine Bone Plate and Screw Systems are safe and effective for its intended use and substantially equivalent to

the predicate devices.

3.7 Substantially Equivalent Conclusion

As compared with predicate devices, equivalence for Double Engine Bone Plate and Screw Systems are based on similarities of intended use, material, physical characteristics, geometric design, and mechanical strength. Therefore, Double Engine believes that there are sufficient evidences to conclude that the Double Engine Bone Plate and Screw Systems are substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Xiamen Double Engine Medical Material Co., Ltd.
% Mr. Da Zeng
No.218, Houxiang Road, Haicang District
Xiamen, 361022
China

Letter dated: April 19, 2013

Re: K130108
Trade/Device Name: Double Engine Bone Plate and Bone Screw Systems
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 14, 2013
Received: April 15, 2013

Dear Mr. Da Zeng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Statement of Intended Use

510(k) Number: K130108

Device Name: Double Engine Bone Plate and Bone Screw Systems

Intend Use Statement:

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☒ PRESCRIPTION USE ☐ OVER-THE-COUNTER USE

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S
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Division of Orthopedic Devices